

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF ILLINOIS  
EAST ST. LOUIS DIVISION**

**SHELLEY CAREY,**

**Plaintiff,**

**v.**

**Case No.: 3:09-cv-10103**

**BAYER CORPORATION,  
BAYER HEALTHCARE LLC, and  
BAYER HEALTHCARE  
PHARMACEUTICALS, INC.,**

**Defendants.**

**COMPLAINT**

Plaintiff brings this action on behalf of herself and on behalf of all others similarly situated. The action is against Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., and Bayer Healthcare, LLC (“collectively “Defendants”).

**PARTIES**

**A. PLAINTIFF**

1. Plaintiff Shelley Carey is a resident and citizen of the State of Ohio.
2. Plaintiff alleges an amount in controversy in excess of seventy-five thousand dollars (\$75,000.00), exclusive of interest and costs.

**B. DEFENDANTS**

3. Defendant Bayer Corporation is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.
4. Defendant Bayer Healthcare LLC is, and all relevant times was, a limited liability corporation organized under the laws of the state of Delaware with its headquarters and principal place of business at 555 White Plains Road, Tarrytown, New York 10591.

5. Defendant Bayer Healthcare LLC is wholly owned by defendant Bayer Corporation.

6. Defendant Bayer Corporation is the sole member of Bayer Healthcare LLC. Defendant Bayer Healthcare LLC owns 100% of Schering Berlin, which owns 100% of Bayer Healthcare Pharmaceuticals, Inc. As such, Defendant Bayer Corporation is a parent of Defendant Bayer Healthcare Pharmaceuticals, Inc.

7. Defendant Bayer Healthcare Pharmaceuticals, Inc. is a Delaware corporation organized under the laws of the state of Delaware with its headquarters and principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000.

8. Defendant Bayer Healthcare Pharmaceuticals, Inc. was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc., and is the same corporate entity as Berlex, inc and Berlex Laboratories, Inc.

9. Defendant Bayer Healthcare Pharmaceuticals, Inc. is the holder of the approved New Drug Application (“NDA”) for Yaz.

10. Defendant Bayer Healthcare Pharmaceuticals, Inc. is the holder of the approved New Drug Application (“NDA”) for Yasmin.

11. Defendant Bayer Healthcare Pharmaceuticals, Inc. is, and at relevant times was engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yaz/Yasmin. At all relevant times, Defendant Bayer Healthcare Pharmaceuticals, Inc. conducted regular and sustained business in Illinois by selling and distributing its products in Illinois and engaged in substantial commerce and business activity in Illinois.

12. Defendant Bayer Healthcare Pharmaceuticals, Inc. is a corporate successor to Berlex Laboratories, Inc. (“Berlex”), which was formerly known as Berlex, Inc., and, as such, is obligated for its predecessor’s liabilities. Berlex was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling, either directly and indirectly through third parties or related entities, the drug Yaz/Yasmin. Berlex Laboratories, Inc. and Berlex, Inc. were integrated into Bayer Healthcare AG and operate as an integrated specialty pharmaceuticals business under Bayer Healthcare Pharmaceuticals, Inc.

13. Defendants Bayer Corporation, Bayer Healthcare LLC, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Berlex Laboratories, inc., and Berlex, Inc. shall be referred to herein, individually by name or jointly and collectively, as “Bayer” or “Bayer Defendants.”

14. At relevant times, Bayer was engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yaz/Yasmin. At relevant times, Bayer conducted regular and sustained business in Illinois by selling and distributing its products in Illinois and engaged in substantial commerce and business activity in Illinois.

15. Jurisdiction and venue are proper under the United States Constitution as well as under Illinois law regarding personal jurisdiction. Defendants have transacted substantial and continuous business in the State of Illinois, have committed tortuous acts and deceptive practices and breached warranties in this state, which form the basis for this cause of action.

16. This court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332, for diversity of citizenship, and Plaintiff claims an amount in controversy exceeding \$75,000.00.

17. The applicable statute of limitations is tolled based on Defendants' fraudulent concealment of the dangers and adverse side effects of the drug Yaz/Yasmin from Plaintiff as more fully stated herein. Additionally, for the reasons stated herein, Defendants are equitably stopped from raising the statute of limitations defense.

### **FACTUAL BACKGROUND**

18. Plaintiff brings this case against Defendants for damages associated with Plaintiff's ingestion of the pharmaceutical drug Yaz/Yasmin (ethinyl estradiol and drospirenone), an oral contraceptive designed, manufactured, marketed and distributed by Defendants. Specifically, as a direct result of her use of Yaz/Yasmin, Plaintiff suffered cardiothrombotic injury.

19. Plaintiff did not know, nor could have reasonably discovered through the use of reasonable diligence, that Yaz/Yasmin wrongfully caused her to suffer injuries and that she had a claim against Defendants until less than two years from the date of filing this action.

### **Bayer's Combined Oral Contraceptives – Yaz and Yasmin**

20. Yaz and Yasmin are birth control pills manufactured and marketed by Defendants. They are combination oral contraceptives, or "COCs," meaning they contain an estrogen component and progestin component. These steroidal components work together in COCs to suppress ovulation, fertilization and implantation, and, thus, they prevent pregnancy.

21. The Food and Drug Administration ("FDA") approved Yaz and Yasmin for marketing in 2006 and 2001, respectively.

### **Yaz and Yasmin contain a "Fourth Generation" Progestin**

22. The estrogen component in Yaz/Yasmin is known generically as ethinyl estradiol. The progestin component is known as drospirenone. Yasmin contains 0.03 milligrams of ethinyl

estradiol, and Yaz contains 0.02 milligrams of ethinyl estradiol. Both products contain 3 milligrams of drospirenone.

23. Yaz and Yasmin are different from other combined hormonal birth control pills in that they contain drospirenone. Drospirenone is a progestin that is unlike other progestins available in the United States. No combined hormonal birth control pills containing drospirenone have been marketed in the United States prior to Yaz/Yasmin.

24. Shortly after the introduction of combined oral contraceptives in the 1960's, doctors and researchers found that women using birth control pills had a higher risk of blood clots, heart attacks and strokes than women not using birth control pills. As a result, the various brands of birth control pills were reformulated to reduce the amounts of estrogen. As the amounts of estrogen levels were reduced, so, too, did the risk of blood clots, heart attacks and strokes.

25. During this time, new progestins were being developed, which became known as "second generation" progestins (e.g. lovenorgestrel). These second generation progestins, when combined with the lower amounts of the estrogen, ethinyl estradiol, helped reduce the risk of blood clots, heart attacks and strokes and were considered safer for women.

26. During the 1990's, new "third generation" progestins were developed. Unfortunately, these third generation progestins (e.g. gestodene and desogestrel) have been associated with a greater risk of blood clots in the deep veins (deep venous thrombosis or "DVT") and lungs (pulmonary embolism or "PE"). As a result of this increased risk of blood clots, the FDA has required that products containing third generation progestins include a warning of the potentially increased risk of thrombosis.

27. Yaz and Yasmin contain the same estrogen component, ethinyl estradiol, which has been used in the lower-dose birth control pills for decades.

28. However, drospirenone is a new type of progestin and is considered a “fourth generation” progestin. No other birth control pills contain drospirenone, except for a recently approved generic version of Yaz/Yasmin marketed under the trade name Ocella.

29. Because drospirenone is new, there is insufficient data available to support its safe use, particularly when compared with second generation progestins. In fact, studies performed prior to FDA approval indicate that drospirenone has certain effects that are different from, and potentially more dangerous than, those of traditional second generation progestins.

30. One possible mechanism of action is that drospirenone causes an increase in potassium levels in the blood, which, if the potassium levels become too high, can lead to a condition known as hyperkalemia. Hyperkalemia can cause heart rhythm disturbances, such as extrasystolies, pauses or bradycardia. If left untreated, hyperkalemia can be fatal. If hyperkalemia disrupts the normal heart rhythms, the flow of blood through the heart can be slowed to the point that it permits blood clots to form. Blood clots in the heart can lead to heart attacks, or the clots can break off and travel to the lungs where they can cause heart attacks, or they can travel to the brain and cause strokes.

31. During the brief time that Yaz/Yasmin have been sold in the United States, hundreds of reports of injury and death have been submitted to the FDA in association with Defendants’ products.

**Establishing the dangers associated with “Fourth Generation” Progestin**

32. In April 2002, the British Medical Journal reported that the Dutch College of General Practitioners recommended that older second generation birth control pills be prescribed in lieu of Yasmin as a result of 40 cases of venous thrombosis among women taking Yasmin.

33. In February 2003, a paper entitled “Thromboembolism Associated with the New Contraceptive Yasmin” was published in the British Medical Journal detailing a Netherlands

Pharmacovigilance Centre report of five additional reports of thromboembolism, including two resulting in death, where Yasmin was suspected as the cause.

34. In fact, in less than a five-year period, from the first quarter of 2004 through the third quarter of 2008, more than 50 reports of death among users of Yaz/Yasmin were filed with the FDA.

35. These reports include deaths associated with cardiac arrhythmia, cardiac arrest, intracardiac thrombus, heart attack and stroke in women in their childbearing years.

36. Some reported death occurred in women as young as 17 years old.

37. Significantly, reports of elevated potassium levels are frequently included among the symptoms of those suffering death while using Yaz/Yasmin.

38. Two recent studies, dated August 2009, have found significantly increased risks associated with Yaz and Yasmin over other types of birth control pills. The first assessed the risk of venous thrombosis in women who take hormonal contraception and was conducted on women ages 15-49 with no history of heart disease or any other malignant disease. The study concluded “oral contraceptives with...drospirenone were associated with a significantly higher risk of venous thrombosis than oral contraceptives with evonorgestrel.” Lidegaard, et. al. Hormonal contraception and risk of venous thromboembolism: national follow-up study, BMJ 2009;339:b2890.

39. The second recent study found that Yaz and Yasmin users have twice the risk of a clotting event than users of birth control pills that contain levonorgestral. Vandenbroucke, et. al., The venous thrombotic risk of oral contraceptives, effects of estrogen dose and progestogen type: results of the MEGA case-control study. BMJ 2009;339:b2921.

**Over-Promotion of Yasmin and Yaz**

40. Defendants market Yaz/Yasmin as providing the same efficacy as other birth control pills in preventing pregnancy but with additional benefits.

41. However, because Yaz/Yasmin contains the fourth generation progestin drospirenone, they present additional health risks not associated with other birth control pills.

42. Despite the foregoing evidence of increased risks of suffering thrombotic events, Defendants, through their marketing and advertising, urged young women to use their products, and in many cases, switch from products that presented a safer alternative.

43. Bayer did so in many respects through deceptive and misleading advertising. For example, prior to its sale to Defendant Bayer in 2006, Defendant Berlex promoted Yasmin's fourth generation progestin, drospirenone, by stating, "Ask about Yasmin, and the difference a little chemistry can make."

44. In response, on July 10, 2003, the FDA objected to the characterization that drospirenone was more beneficial compared to the progestin used in other combined oral contraceptives and issued a warning letter stating, "FDA is not aware of substantial evidence of substantial clinical experience demonstrating that Yasmin is superior to other COCs or that the drospirenone in Yasmin is clinically beneficial. On the contrary, FDA is aware of the added clinical risks associated with drospirenone [.]". The FDA's warning letter continued by stating that the advertisement failed "to communicate that the potential to increase potassium is a risk" or that "increased serum potassium can be dangerous."

45. Recently, Defendants advertised that its product Yaz/Yasmin was indicated for treatment of premenstrual syndrome or "PMS," as opposed to the less serious condition of premenstrual dysphoric disorder or "PMDD." Defendants also advertised that Yaz/Yasmin contained the added benefit of preventing or reducing acne.

46. In response, on October 3, 2008, the FDA issued another warning letter to Defendant Bayer for the misleading advertisement and reiterated that the marketing was misleading because it promoted Yaz/Yasmin for medical conditions beyond the limits of the FDA approval. The FDA added that “Yaz/Yasmin has additional risks because it contains the progestin, drospirenone...which can lead to hyperkalemia in high risk patients, which may result in potentially serious heart and health problems.”

47. The FDA further warned in its October 3, 2008, letter that Yaz/Yasmin “does not result in completely clear skin” and that Defendants’ “TV Ads misleadingly overstate the efficacy of the drug.”

48. Indeed, the FDA felt Defendants’ over-promotion was so severe that it required Bayer to run new TV advertisements to correct the previous misleading Yaz/Yasmin advertisements regarding acne and premenstrual syndrome.

49. Bayer ultimately agreed to spend at least \$20 million on corrective TV advertisements and to submit all Yaz/Yasmin advertisements to the FDA for advanced screening for the next six years.

**Plaintiff’s Use of Yaz/Yasmin and Resulting Injuries**

50. As a result of Defendants’ claims regarding the efficacy and safety of Yaz/Yasmin, Plaintiff’s medical providers prescribed, and Plaintiff began using Yaz/Yasmin.

51. As a direct and proximate result of using Yaz/Yasmin, Plaintiff suffered personal injuries.

52. Plaintiff did not know, nor could she have reasonably discovered through the use of reasonable diligence, that Yaz/Yasmin wrongfully caused her to suffer injuries and that she had claims against Defendants until less than two years from the date of filing this action.

53. Prior to Plaintiff's use of Yaz/Yasmin, Defendants knew or should have known that use of Yaz/Yasmin created a higher risk of cardiovascular and gallbladder injuries than other oral contraceptives on the market, including, but not limited to, second generation oral contraceptives and that, when taken as directed, such use was unreasonably dangerous to consumers.

54. Therefore, at the time Plaintiff used Yaz/Yasmin, Defendants knew or should have known that the use of Yaz/Yasmin created an increased risk to consumers of serious personal injury, including pulmonary embolism (PE), deep venous thrombosis (DVT), heart attack, stroke and even death.

55. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of Yaz/Yasmin, Defendants failed to warn Plaintiff and/or her health care providers of said serious risks before she used the product.

56. Had Plaintiff and/or her health care providers known the risks and dangers associated with Yaz/Yasmin, she would not have used Yaz/Yasmin and would not have suffered from her injuries.

57. As a direct and proximate result of her use of Yaz/Yasmin, Plaintiff suffered personal injuries, including, but not limited to, conscious pain and suffering.

58. As a direct and proximate result of Plaintiff's use of Yaz/Yasmin, Plaintiff has suffered and will continue to suffer pecuniary losses.

### **COUNT I**

#### **STRICT PRODUCT LIABILITY – DEFECTIVE DESIGN (Failure to Warn)**

59. Plaintiff repeats and re-alleges the allegations set forth in the paragraphs above as if fully set forth herein.

60. The Yaz/Yasmin manufactured and/or supplied by the Defendants was unaccompanied by proper warnings regarding all possible adverse side-effects and the comparative severity and duration of such adverse effects; the warnings given did not accurately reflect the severity or duration of the adverse side effects or the true potential and/or likelihood or rate of the side effects. Defendants failed to perform adequate testing in that adequate testing would have shown that Yaz/Yasmin possessed serious potential side effects with respect to which full and proper warnings accurately and fully reflecting symptoms, scope and severity should have been made with respect to the use of Yaz/Yasmin. Had the testing been adequately performed, the product would have been allowed to enter the market, if at all, only with warnings that would have clearly and completely identified the risks and dangers of the drug.

61. The Yaz/Yasmin manufactured and/or distributed and/or supplied by Defendants was defective due to inadequate post-marketing warning or instruction because Defendants failed to provide adequate warnings to users or consumers of Yaz/Yasmin and continued to aggressively promote Yaz/Yasmin.

62. As the proximate cause and legal result of the defective condition of Yaz/Yasmin as manufactured and/or supplied and/or distributed by Defendants, and as a direct and legal result of the conduct of Defendants described herein, Plaintiff has been damaged.

WHEREFORE, the Plaintiff demands judgment in her favor and against Defendants in a sum in excess of \$75,000; for costs herein incurred; attorneys fees; for such other and further relief as this Court deems just and proper.

**COUNT II**

**STRICT PRODUCT LIABILITY  
(Pursuant to Restatement Second of Torts 402a (1965))**

63. Plaintiff repeats and re-alleges the allegations set forth in the paragraphs above as if fully set forth herein.

64. The Yaz/Yasmin manufactured and/or distributed and/or supplied by Defendants was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, the foreseeable risks exceeded the benefits associated with the design and formulation of the drug.

65. Alternatively, the Yaz/Yasmin manufactured and/or distributed and/or supplied by Defendants was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect and more dangerous than alternative drugs available for use as an oral contraceptive.

66. There existed, at all times material hereto, safer alternative medications.

67. Defendants did not perform adequate testing upon Yaz/Yasmin. Adequate testing would have revealed that Yaz/Yasmin causes serious adverse effects with respect to which full and proper warnings accurately and fully reflecting symptoms, scope and severity should have been made.

68. The Yaz/Yasmin manufactured, designed, marketed, distributed and/or sold by Defendants was unaccompanied by proper and adequate warnings regarding adverse effects associated with the use of Yaz/Yasmin, and the severity and duration of such adverse effects; the warnings given did not accurately reflect the symptoms, scope or severity of adverse effects and did not accurately relate the lack of efficacy.

69. Defendants did not warn the FDA of material facts regarding the safety and efficacy of Yaz/Yasmin, which facts Defendants knew or should have known.

70. The Yaz/Yasmin manufactured and/or distributed and/or supplied by Defendants was defective due to inadequate post-marketing warning or instruction because, after the Defendants knew or should have known of the risk of injury from Yaz/Yasmin, they failed to provide adequate warnings to users or consumers of Yaz/Yasmin and continued to promote Yaz/Yasmin.

71. As a result of the defective condition of Yaz/Yasmin, Plaintiff has suffered damage and injury.

WHEREFORE, the Plaintiff demands judgment in her favor and against Defendants in a sum in excess of \$75,000; for costs herein incurred; attorneys fees; for such other and further relief as this Court deems just and proper.

### **COUNT III**

#### **INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS**

72. Plaintiff repeats and re-alleges the allegations set forth in the paragraphs above as if fully set forth herein.

73. The acts, omissions, and representations of the Defendants regarding the manufacturing, distribution and marketing of Yaz/Yasmin as described in the foregoing paragraphs were intentional, reckless, extreme and outrageous. Defendants intentionally engaged in extreme and outrageous conduct when they intentionally and/or recklessly marketed Yaz/Yasmin and then intentionally and/or recklessly concealed material information about Yaz/Yasmin's potential serious adverse effects from Plaintiff and her physicians, hospitals, and medical providers.

74. Defendants knew that Plaintiff would suffer mental distress and anxiety upon

learning that Yaz/Yasmin possessed a likelihood of serious adverse effects and complications or death from significant increased risk of cardiothrombotic injury, which was caused by Defendants' drug, Yaz/Yasmin.

75. As a result of Defendants' misconduct, Plaintiff sustained and will continue to sustain emotional and mental distress and anxiety.

WHEREFORE, the Plaintiff demands judgment in her favor and against Defendants in a sum in excess of \$75,000; for costs herein incurred; attorneys fees; for such other and further relief as this Court deems just and proper.

#### **COUNT IV**

##### **NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS**

76. Plaintiff repeats and re-alleges the allegations set forth in the paragraphs above as if fully set forth herein.

77. Defendants negligently and carelessly manufactured, sold and distributed to Plaintiff Yaz/Yasmin, which was defective.

78. Defendants negligently and carelessly concealed the defective nature of Yaz/Yasmin from Plaintiff, her physicians, hospitals, and medical providers.

79. Defendants negligently and carelessly misrepresented the usefulness, quality and safety of Yaz/Yasmin to Plaintiff, her physicians, hospitals, and medical providers.

80. The Defendants' negligence and carelessness directly impacted the Plaintiff in that she was induced to purchase and ingest the defective and dangerous Yaz/Yasmin.

81. As a direct result of Defendants' misconduct alleged herein, Plaintiff has suffered and will continue to suffer emotional and mental distress and anxiety from the fear of knowing there is a likelihood of serious complications or death from significant increased risk of cardiothrombotic injury, which was caused by Defendants' drug, Yaz/Yasmin.

WHEREFORE, the Plaintiff demands judgment in her favor and against Defendants in a sum in excess of \$75,000; for costs herein incurred; attorneys fees; for such other and further relief as this Court deems just and proper.

**COUNT V**

**COMMON LAW FRAUD**

82. Plaintiff repeats and re-alleges the allegations of the prior paragraphs as if set forth at length herein.

83. Defendants made material representations that were false and that were either known to be false when made or were asserted without knowledge of their truth. Defendants had in its possession adverse drug event reports, drug studies, and other documentation about Yaz/Yasmin and yet made the following misrepresentations:

- a. Misrepresentations regarding the frequency of Yaz/Yasmin-related adverse event reports or occurrences in the Yaz/Yasmin label, package insert or PDR label;
- b. Misrepresentations as to the existence, occurrence and frequency of occurrences, severity and extent of the overall risks of Yaz/Yasmin;
- c. Misrepresentations as to the efficacy of Yaz/Yasmin;
- d. Misrepresentations as to the number of adverse events and deaths reported with the use of Yaz/Yasmin;
- e. Misrepresentations regarding the nature, seriousness, and severity of adverse events reported with the use of Yaz/Yasmin.

84. Defendants intended that these misrepresentations be relied upon by physicians, including Plaintiff's physicians, healthcare providers and consumers. Plaintiff did rely upon the misrepresentations that caused Plaintiff's injuries.

85. Defendants' misrepresentations were the proximate and/or producing cause of Plaintiff's injuries.

WHEREFORE, the Plaintiff demands judgment in her favor and against Defendants in a sum in excess of \$75,000; for costs herein incurred; for such other and further relief as this Court deems just and proper; and demands that the issues herein contained be tried to a jury.

## **COUNT VI**

### **NEGLIGENCE**

86. Plaintiff repeats and re-alleges the allegations of the prior paragraphs as if set forth at length herein.

87. Defendants owed Plaintiff legal duties in connection with its development, manufacture, and distribution of Yaz/Yasmin. Defendants breached those duties, proximately causing Plaintiff's injuries. Specifically, Defendants failed to meet its duty to use reasonable care in the testing, creating, designing, manufacturing, labeling, packaging, marketing, selling, and warning of Yaz/Yasmin. Defendants are liable for acts and/or omissions amounting to negligence, gross negligence and/or malice including, but not limited to the following:

- a. Failure to adequately warn Plaintiff and Plaintiff's physicians of the known or reasonably foreseeable danger that Plaintiff would suffer a serious injury or death by ingesting Yaz/Yasmin;
- b. Failure to adequately warn Plaintiff and Plaintiff's physicians of the known or reasonably foreseeable danger that Plaintiff would suffer a serious injury or death by ingesting Yaz/Yasmin in unsafe doses;
- c. Failure to use reasonable care in testing and inspecting Yaz/Yasmin so as to ascertain whether or not it was safe for the purpose for which it was designed, manufactured and sold;
- d. Failure to use reasonable care in implementing and/or utilizing a reasonably safe design in the manufacture of Yaz/Yasmin;
- e. Failure to use reasonable care in the process of manufacturing Yaz/Yasmin in a reasonably safe condition for the use for which it was intended;
- f. Failure to use reasonable care in the manner and method of warning Plaintiff and Plaintiff's physicians as to the danger and risks of using Yaz/Yasmin in unsafe doses;

g. Such further acts and/or omissions that may be proven at trial.

88. The above-described acts and/or omissions of Defendants were a direct and proximate cause of the severe, permanent and disabling injuries and resulting damages to Plaintiff.

WHEREFORE, the Plaintiff demands judgment in her favor and against Defendants in a sum in excess of \$75,000; for costs herein incurred; for such other and further relief as this Court deems just and proper; and demands that the issues herein contained be tried to a jury.

### **COUNT VII**

#### **NEGLIGENT MISREPRESENTATION**

89. Plaintiff repeats and re-alleges the allegations of the prior paragraphs as if set forth at length herein.

90. Defendants failed to communicate to Plaintiff and/or the general public that the ingestion of Yaz/Yasmin could cause serious injuries after they became aware of such risks. Instead, Defendants represented in their marketing that Yaz/Yasmin was safe and effective.

91. Plaintiff bring this cause of action against Defendants under the theory of negligent misrepresentation for the following reasons:

- a. Defendants, individually, and through its agents, representatives, distributors and/or employees, negligently misrepresented material facts about Yaz/Yasmin in that they made such misrepresentations when they knew or reasonably should have known of the falsity of such misrepresentations. Alternatively, Defendants made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations;
- b. The above misrepresentations were made to Plaintiff, as well as the general public;
- c. Plaintiff and her healthcare providers justifiably relied on Defendants' misrepresentations; and

- d. Consequently, Plaintiff ingested Yaz/Yasmin to Plaintiff's detriment. Defendants' negligent misrepresentations proximately caused Plaintiff's injuries and monetary losses.

WHEREFORE, the Plaintiff demands judgment in her favor and against Defendants in a sum in excess of \$75,000; for costs herein incurred; for such other and further relief as this Court deems just and proper; and demands that the issues herein contained be tried to a jury.

### **COUNT VIII**

#### **FRAUDULENT MISREPRESENTATION**

92. Plaintiff repeats and re-alleges the allegations of the prior paragraphs as if set forth at length herein.

93. Defendants are engaged in the business of selling Yaz/Yasmin. By their advertising, labels, or otherwise, Defendants has made to Plaintiff, and the public, a misrepresentation of a material fact concerning the character or quality of Yaz/Yasmin.

94. Plaintiff justifiably relied on Defendants' misrepresentations in purchasing Yaz/Yasmin. Plaintiff has suffered physical harm proximately caused by Defendants' misrepresentations regarding the character or quality of Yaz/Yasmin.

WHEREFORE, the Plaintiff demands judgment in her favor and against Defendants in a sum in excess of the jurisdictional requirement of this Court; for costs herein incurred; for such other and further relief as this Court deems just and proper; and demands that the issues herein contained be tried to a jury.

### **COUNT IX**

#### **EXPRESS WARRANTY**

95. Plaintiff repeats and re-alleges the allegations of the prior paragraphs as if set forth at length herein.

96. Defendants are merchants and/or sellers of Yaz/Yasmin. Defendants sold Yaz/Yasmin to consumers, including Plaintiff, for the ordinary purpose for which such drugs are used by consumers. Defendants made representations to Plaintiff about the quality or characteristics of Yaz/Yasmin by affirmation of fact, promise and/or description. The representations by Defendants became part of the basis of the bargain between Defendants and Plaintiff. Yaz/Yasmin did not comport with the representations made by Defendants in that it was not safe for the use for which it was marketed. This breach of duty by Defendants was a proximate cause of the injuries and monetary loss suffered by Plaintiff.

WHEREFORE, the Plaintiff demands judgment in her favor and against Defendants in a sum in excess of the jurisdictional requirement of this Court; for costs herein incurred; for such other and further relief as this Court deems just and proper; and demands that the issues herein contained be tried to a jury.

### **COUNT X**

#### **IMPLIED WARRANTY**

97. Plaintiff repeats and re-alleges the allegations of the prior paragraphs as if set forth at length herein.

##### **A. WARRANTY OF MERCHANTABILITY**

98. Defendants are merchants and/or sellers of Yaz/Yasmin. Plaintiff purchased Yaz/Yasmin from Defendants and used Yaz/Yasmin for the ordinary purpose for which it is used by consumers. At the time it was purchased by Plaintiff, Yaz/Yasmin was not fit for the ordinary purpose for which such drugs are used. Yaz/Yasmin was not fit for the ordinary purpose for which such drugs are used because it was not manufactured, designed or marketed in a manner to accomplish its purpose safely. Defendants' breach of its implied warranty of merchantability caused Plaintiff's injuries and monetary losses.

**B. WARRANTY OF FITNESS**

99. Defendants sold Yaz/Yasmin to Plaintiff with the knowledge that Plaintiff was purchasing Yaz/Yasmin for a particular purpose. Further, Defendants knew, or should have known, that Plaintiff was relying on Defendants' skill or judgment to select goods fit for Plaintiff's purpose.

100. Defendants delivered goods that were unfit for Plaintiff's particular purpose, and thus breached its implied warranty of fitness. Defendants' failure to select and sell a product which was reasonably safe for its intended use proximately caused Plaintiff's injuries and monetary losses.

WHEREFORE, the Plaintiff demands judgment in her favor and against Defendants and Co. in a sum in excess of the jurisdictional requirement of this Court; for costs herein incurred; attorneys fees; for such other and further relief as this Court deems just and proper; and demands that the issues herein contained be tried to the bench.

Respectfully Submitted,

/s/ JOHN J. DRISCOLL  
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